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# CANCER FACTS

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National Cancer Institute • National Institutes of Health

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## Questions and Answers About Tamoxifen

### 1. What is tamoxifen?

Tamoxifen is a medication in pill form that interferes with the activity of estrogen (a female hormone). Tamoxifen has been used for more than 20 years to treat patients with advanced breast cancer. It has also been used as adjuvant, or additional, therapy following surgery or radiation therapy for early stage breast cancer. Tamoxifen has recently been found to reduce the incidence of breast cancer in women at high risk of developing this disease. Tamoxifen continues to be studied for the prevention of breast cancer. It is also being studied in the treatment of several other types of cancer.

### 2. How does tamoxifen work on breast cancer?

Estrogen promotes the growth of breast cancer cells. Tamoxifen works against the effects of estrogen on these cells. It is often called an "anti-estrogen." As a treatment for breast cancer, the drug slows or stops the growth of cancer cells that are already present in the body. As adjuvant therapy, tamoxifen has been shown to help prevent the original breast cancer from returning and also prevent the development of new cancers in the opposite breast.

### 3. Are there other beneficial effects of tamoxifen?

While tamoxifen acts *against* the effects of estrogen in breast tissue, it acts *like* estrogen in other body systems. This means that women who take tamoxifen may derive many of the beneficial effects of menopausal estrogen replacement therapy, such as a lowering of blood cholesterol and a slowing of bone loss (osteoporosis).

### 4. Can tamoxifen prevent breast cancer?

Research has shown that when tamoxifen is used as adjuvant therapy for early stage breast cancer, it not only prevents the recurrence of the original cancer but also prevents the development of new cancers in the opposite breast. Based on these findings, the National Cancer Institute (NCI) funded a large research study, the Breast Cancer Prevention Trial (BCPT) conducted by the National Surgical Adjuvant Breast and Bowel Project (NSABP), to determine the usefulness of tamoxifen in preventing breast cancer in

women who have an increased risk of developing the disease. Results from this study showed a 49 percent reduction in diagnoses of invasive breast cancer among women who took tamoxifen. Women who took tamoxifen also had 50 percent fewer diagnoses of noninvasive breast tumors, such as ductal or lobular carcinoma in situ. However, there are some risks associated with tamoxifen, some even life threatening. The decision to take tamoxifen is an individual one in which the woman and her doctor must carefully consider the benefits and risks of therapy.

Women with an increased risk of developing breast cancer have the option to consider taking tamoxifen to reduce their chance of developing this disease. They may also consider participating in the upcoming Study of Tamoxifen and Raloxifene that will compare tamoxifen with the osteoporosis prevention drug raloxifene, which could have similar breast cancer risk reduction properties, but might be associated with fewer adverse effects.

At this time, there is no evidence that tamoxifen is beneficial for women who do not have an increased risk of breast cancer.

**5. What is the Study of Tamoxifen and Raloxifene (STAR), and how can a woman learn more about it?**

The National Surgical Adjuvant Breast and Bowel Project (NSABP), a component of NCI's Clinical Trials Cooperative Group Program, has launched a new breast cancer study. The new trial, known as STAR, began recruiting participants in June 1999. It will involve about 22,000 postmenopausal women who are at least 35 years old and are at increased risk for developing breast cancer. The study is designed to determine whether raloxifene, a drug similar to tamoxifen, is also effective in reducing the chance of developing breast cancer in women who have not had the disease, and whether the drug has benefits over tamoxifen, such as fewer side effects.

Women can learn more about the STAR trial in several ways. They can call NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237). The number for deaf and hard of hearing callers with TTY equipment is 1-800-332-8615. Information is also available on NSABP'S Web site at <http://www.nsabp.pitt.edu> or NCI's clinical trials Web site at <http://cancertrials.nci.nih.gov> on the Internet.

**6. Does tamoxifen cause blood clots?**

Data from large treatment studies suggest that there is a small increase in the number of blood clots in women taking tamoxifen, particularly in women who are receiving anticancer drugs (chemotherapy) along with tamoxifen. The total number of women who have experienced this side effect is small. Women in the BCPT who took tamoxifen also had an increased chance of developing blood clots. The risk of having a blood clot due to tamoxifen is similar to the risk of blood clots for women on single-agent estrogen replacement therapy.

**7. Does tamoxifen cause uterine cancer?**

The BCPT found that women taking tamoxifen had more than twice the chance of developing uterine cancer compared with women on placebo (an inactive substance that looks the same as, and is administered in the same way as, tamoxifen). The risk of uterine cancer in women taking tamoxifen was in the same range as (or less than) the risk in postmenopausal women taking single-agent estrogen replacement therapy. Additional studies are under way to define more clearly the role of other risk factors for uterine cancer, such as prior hormone use, in women receiving tamoxifen.

Like many cancers, uterine cancer is potentially life threatening. Most of the uterine cancers that have occurred during studies of women taking tamoxifen have been found in the early stages, and treatment was usually effective. However, breast cancer patients who developed uterine cancer while taking tamoxifen have died from the disease. Abnormal vaginal bleeding and lower abdominal (pelvic) pain are two symptoms of the disease. Women on tamoxifen should see their doctor if they experience these symptoms.

**8. Does tamoxifen cause eye problems?**

As women age, they are more likely to develop cataracts (a clouding of the lens inside the eye). Women taking tamoxifen appear to be at increased risk for developing cataracts. Other eye problems, such as corneal scarring or retinal changes, have been reported in a few patients.

**9. Does tamoxifen cause other types of cancer?**

There have been a few reports of liver cancer and reports of other liver toxicities that have occurred in women taking tamoxifen. Although tamoxifen can cause liver cancer in particular strains of rats, it is not known to cause liver cancer in humans. Tamoxifen did not cause liver cancer in the BCPT. It is clear that tamoxifen can sometimes cause other liver toxicities in women, which rarely can be severe or life threatening. Doctors may order blood tests from time to time to check liver function.

Although one study suggested a possible increase in cancers of the digestive tract among women receiving tamoxifen for breast cancer, other trials, including the BCPT, have not shown an association between tamoxifen and these cancers.

Studies such as the BCPT show no increase in cancers other than uterine cancer. This potential risk is being evaluated.

**10. Should women taking tamoxifen avoid pregnancy?**

Yes. Tamoxifen may make premenopausal women more fertile, but doctors advise women on tamoxifen to avoid pregnancy because animal studies have suggested that the use of tamoxifen in pregnancy can cause fetal harm. Women who have questions about fertility, birth control, or pregnancy should discuss their concerns with their doctor.

**11. What are some of the more common side effects of taking tamoxifen?**

In general, the side effects of tamoxifen are similar to some of the symptoms of menopause. The most common side effects are hot flashes and vaginal discharge. Some women experience irregular menstrual periods, dizziness, headaches, fatigue, loss of appetite, nausea and/or vomiting, vaginal dryness or bleeding, and irritation of the skin around the vagina. As is the case with menopause, not all women who take tamoxifen have these symptoms.

**12. Does tamoxifen cause a woman to begin menopause?**

Tamoxifen does not cause a woman to begin menopause, although it can cause some symptoms that are similar to those that may occur during menopause. In most premenopausal women taking tamoxifen, the ovaries continue to act normally and produce female hormones (estrogens) in the same or slightly increased amounts.

**13. Do the benefits of tamoxifen in treating breast cancer outweigh its risks?**

The benefits of tamoxifen as a treatment for breast cancer are firmly established and far outweigh the potential risks. Women concerned about the risks and benefits of medications they are taking are encouraged to discuss these concerns with their doctor.

**14. How long should a woman take tamoxifen for the treatment of breast cancer?**

Women with advanced breast cancer may take tamoxifen for varying lengths of time depending on their response to prior treatment and other factors. When used as adjuvant therapy for early stage breast cancer, tamoxifen is generally prescribed for 5 years. However, the ideal length of treatment with tamoxifen is not known.

Two studies have confirmed the benefit of taking tamoxifen daily for 5 years. These studies compared 5 years of treatment with tamoxifen with 10 years of treatment. When taken for 5 years, the drug prevents the recurrence of the original breast cancer and also prevents the development of a second primary cancer in the opposite breast. Taking tamoxifen for longer than 5 years is not more effective than 5 years of therapy.

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**Sources of National Cancer Institute Information**

**Cancer Information Service**

Toll-free: 1-800-4-CANCER (1-800-422-6237)

TTY (for deaf and hard of hearing callers): 1-800-332-8615

**NCI Online**

***Internet***

Use <http://www.cancer.gov> to reach NCI's Web site.

***CancerMail Service***

To obtain a contents list, send e-mail to [cancermail@icicc.nci.nih.gov](mailto:cancermail@icicc.nci.nih.gov) with the word "help" in the body of the message.

**CancerFax®** fax on demand service

Dial 301-402-5874 and listen to recorded instructions.

**This fact sheet was reviewed on 6/16/99**